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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
04/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,061	SIDNEY ET AL.	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,9,10,13 and 20-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7,9,10,13 and 20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/12/10 has been entered.

2. Claims 1, 6, 7, 9, 10, 13, and 20-30 are all the pending claims for this application.

3. Claim 1 was amended and new Claim 30 was added in the Response of 4/12/10.

4. Claims 1, 6, 7, 9, 10, 13, and 20-30 are all the pending claims in this application.

Information Disclosure Statement

5. The IDS of 4/12/10 has been considered and entered. The initialed and signed 1449 form is attached.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

6. The rejection of Claims 1, 6, 7, 9, 10, 13 and 20-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Claim 30 is joined under this rejection and as being drawn to a composition comprising at least one peptide of eight to thirteen residues in length where the at least one peptide comprises a CTL of the peptide in the Markush group having SEQ ID NO: 527, 673, 846, 627, 139, 859, 502, 53, 55 and/or 807.

The rejection was set forth in the Office Action of 6/30/09 as follows:

"Claim 1 and the dependent claims thereof are interpreted as being drawn to a composition comprising "one or more peptides" originating from any source or any kind of protein so long as the peptide(s) is eight to thirteen residues in length. Additionally, at least one of the peptides in the composition is the CTL epitope of SEQ ID NO: 53, 55, 139, 502, 527, 627, 673, 807, 846, 859 or admixtures thereof. Thus, with the exception of the peptides of SEQ ID NO: 53, 55, 139, 502, 527, 627, 673, 807, 846, 859 or admixtures thereof, the remaining genus of peptides falling within the scope of composition Claim 1 is unlimited in both structure and function. This is a reach-through claim for the genus of all peptides having the only requirement that it is eight to thirteen residues in length. The genus of peptides does not find written support in the specification and prior art.

Claim 18 requires that the peptides comprising the composition of Claim 1 would be useful as a diagnostic reagent, and the specification does not support the genus of peptides meeting this criterion.

Under the Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001) revised training materials 3/29/08), the claimed invention must meet the following criteria as set forth.

a) Actual reduction to practice: The specification discloses compositions comprising immunogenic peptides [0008; 0087; 0090; 0092], and having binding motifs specific for MHC molecules [0008]. The at least one of the one or more peptides is a peptide from an antigen selected from the group consisting of prostate specific antigen (PSA), prostate specific membrane antigen (PSM), hepatitis B virus (HBV) antigen, hepatitis C virus (HCV) antigen, malignant melanoma antigen (MAGE), Epstein Barr virus, human immunodeficiency type-1 (HIV-1), human immunodeficiency type-2 (HIV-2), papilloma virus, Lassa virus, mycobacterium tuberculosis (MT), p53, murine p53 (mp53), CEA, HER2/neu, and tyrosine kinase related protein (TKP) (Claim 13 in the PGPub). Tables 11-29 define: HLA-A1 allele-binding peptides (Table 11); HLA-A2 allele-binding peptides (Table 13); HLA-A3 allele-binding peptides (Table 15); HLA-A24 allele-binding peptides (Table 17); HLA-B7 allele-binding peptides (Table 19); HLA-B44 allele-binding peptides (Table 21); HLA-DQ allele-binding peptides (Table 23); HLA-DR allele-binding peptides (Table 25); and murine MHC class I allele-binding peptides (Table 28) and their respective binding affinities.

The specification does not support compositions comprising just any peptide of eight to thirteen residues in length from just any protein. The peptides of the invention are at a minimum immunogenic and are more specifically MHC binding.

b) Disclosure of drawings or structural chemical formulas: the specification and drawings do not show that applicant was in possession of the genus of just any peptide of eight to thirteen residues in length from just any protein that is included in the composition.

c) Sufficient relevant identifying characteristics: the specification does not identify 1) a complete structure, ii) partial structure, iii) physical and/or chemical properties, or iv) functional characteristics coupled with correlation between structure and function for the genus of just any peptide of eight to thirteen residues in length from just any protein that is included in the composition.

d) Method of making the claimed invention: the specification teaches methods for identifying immunogenic, MHC (HLA)-binding epitopes from immunogenic proteins in the form of peptides that range in size from eight to thirteen residues.

e) Level of skill and knowledge in the art: the screening of proteins for immunogenic epitopes having MHC binding activity and CTL activity was well established at the time of the invention.

f) Predictability in the Art: it is predictable that Applicants could generate any peptide that ranges in size from eight to thirteen residues. It is unpredictable that just any one of the peptides would have a structure that conferred

some property much less a property relevant to binding MHC (HLA) or being a CTL epitope absent a structure function correlation for the peptide. It is unpredictable that just any peptide would have a diagnostic function as a component in a diagnostic composition (See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."; "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." In re Curtis, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)).

Scholnick et al (Trends in Biotechnology, 18(1):34-39, 2000; cited in the PTO 892 form of 1/14/08) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based on sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to function of the structurally related protein (see in particular "Abstract" and Box 2).

Applicants have not demonstrated with sufficient evidence the genus of just any peptide of eight to thirteen residues in length from just any protein that is included in the composition much less where the peptide is a diagnostic peptide comprised in a diagnostic composition."

The rejection was maintained in the Office Action of 1/12/10 as follows:

"Applicants allegations on pp. 6-8 of the Response of 9/30/09 have been considered and are not found persuasive. Applicants allege that in amending Claim 1 to recite that from within the composition a peptide comprising a CTL epitope being selected from the group consisting of SEQ ID NOs: 527, 673, 846, 627, 139, 859, 502, 53, 55, 807, and admixtures thereof, the compositions are now drawn to only those species of peptides in the Markush group.

Response to Arguments

It is correct that the claims recite that the composition would comprise at least one of the CTL peptides of the Markush group. However, it is incorrect that other myriad peptides having no known structure or no known function but being of any eight to thirteen residues in length, could also be present along with the recited CTL peptides. MPEP 2111.02 states in part:

> "The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim."); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). >In Gillette Co. v. Energizer Holdings Inc., 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to "a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades" encompasses razors with more than three blades because the transitional phrase "comprising" in the preamble and the phrase "group of" are presumptively open-ended. "The word comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." Id. In contrast, the court noted the phrase "group consisting of" is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature closed. Id. The court also emphasized that reference to "first," "second," and "third" blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. Id.<"

The rejection is maintained."

Applicants allegations on pp. 6-7 of the Response of 4/12/10 have been considered and are not found persuasive. Applicants allege "Knowing that an Applicant cannot identify each and every element, however subtle, that can be encompassed in a claim, the courts have allowed the use of transitional phrases, such as "comprising," so that Applicants can include unrecited elements in their claimed invention. As applied to the pending claims, the claimed composition must comprise at least one of the recited peptides. It is true that use of "comprising" allows for unrecited elements, but this is the entire nature of use of the term. To follow the Examiner's line of reasoning would suggest that every claim using open-ended terms such as "comprising" or "having" would fail the written description requirement because they would naturally encompass unrecited elements. This is clearly not the standard for satisfying 35 U.S.C. § 112."

Response to Arguments

To re-iterate what has already been established on the record, the claims encompass myriad genii of peptides of 8-13 residues so long as at least one of the peptides in the composition comprises the CTL epitopes having the sequence of SEQ ID NO: 527, 673, 846, 627, 139, 859, 502, 53, 55 and/or 807. Applicants have not demonstrated what the remaining peptides in the composition should be by a structural or functional definition. The comprising language would assuredly encompass unclaimed elements as Applicants urge the Office to believe, but even those elements must be supported by the specification to meet the 112, 1st paragraph written description requirements. Applicants have yet to explain what the remaining examples of peptides in the composition would look like or how they function, with the only

claimed knowledge of those peptides being 8-13 residues in length. The breadth and scope of the allegedly "unrecited" elements, which in this case are other peptides, have not been described in the specification, by introduction thru declaration evidence or any other means.

Finally, where the courts have recently opined on written description for species when generic claims are sought, the Examiner turns to *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.* (Fed. Cir. 2010) (en banc) stating in part:

> "a few broad principles hold across all cases"; "We have made clear that the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement. *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006). Conversely, we have repeatedly stated that actual "possession" or reduction to practice outside of the specification is not enough. Rather, as stated above, it is the specification itself that must demonstrate possession. And while the description requirement does not demand any particular form of disclosure, *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008), or that the specification recite the claimed invention *in haec verba*, a description that merely renders the invention obvious does not satisfy the requirement, *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997)."
>
> "For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus. The problem is especially acute with genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

The rejection is maintained.

Conclusion

7. No claims are allowed.

8. The closest reference art found to read on the CTL epitope of SEQ ID NO: 53, 55, 139, 502, 527, 627, 673, 807, 846, or 859 is Grey et al. (10/817,970 (priority to 4/6/04)) and Baker et al. (11/027,670 (filed 1/3/05)). The references are not effective prior art as Applicants' priority for the sequences to U.S. Provisional Application No. 60/416,207 (filed 10/3/02) antedates the references.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/

Primary Examiner, Art Unit 1643